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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,152	06/15/2001	Giulia Kennedy	097268061663.002	8227

7590 02/27/2004

Chiron Corporation  
Intellectual Property - R440  
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EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/883,152

Applicant(s)

KENNEDY ET AL.

Examiner

Sally A Sakelaris

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See continuation sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 43-59.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

*Carla J. Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER

*Sally A. Sakelaris*  
2/25/04

Continuation of 2. NOTE: The proposed amendment extensively modifies the claims and as a result will not be entered. The recitation of "test cell" instead of "test cell obtained from a cell of a subject", "test sample" to "test cell", "wherein said sample" to "wherein said cell", and "sample of colon" to "colon cell" all change the scope of the claims and as a result requires a new search of the prior art. Furthermore, the amendments to the claims filed on February 4, 2004 does not comply with the requirements for filing claims under the new revised format. While claims 3-11, 14-20, and 22-42 are withdrawn, they are still required to be present in full form, unlike cancelled claims.

Continuation of 5. does NOT place the application in condition for allowance because: The applicant's traversal is on the grounds that the 112 first paragraph enablement rejection standing in the previous final rejection is improper. Applicants submit that "SEQ ID NO:3" and "CLUSTER 9083" "refer to the same gene". While it is possible that "CLUSTER 9083" may be inclusive of "SEQ ID NO:3", it is not clear from the specification that they are analogous terms. It is therefore unpredictable to assume that the overexpression of an entire cluster, not just of SEQ ID NO:3, enables the method with respect to only SEQ ID NO:3. It is not clear what other sequences 9083 includes in addition to SEQ ID NO:3. While applicants inclusion of Tables 2 and 3, and associated arguments are acknowledged, it remains unpredictable to correlate the overexpression of the many sequences of "CLUSTER 9083" necessarily with one of the cluster's sequences. With respect to applicant comments regarding Table 1 and its inclusion, applicant is reminded that the examiner first asserts that while the four samples, are derived from 4 patients, the identity of the patients is unclear(i.e. Table 1 uses "UC#2" to describe a normal patient's colon and a patient with a tumorous colon. As a result it is unclear which UC#2 sample is being portrayed in the second table on page 84). With respect to applicants' set of arguments regarding Figure 1, the examiner asserts that even though the overexpression of cluster #9083 is shown, the specific over-expression of SEQ ID NO:3 is not. Additionally, a p-value or another means to show statistical significance is absent and as a result the figure does not prove to be informative. Lastly, the applicant should note that the examiner's inclusion of the Falzarano and NCI references was meant only to teach a general principle recognized by practioner's of various different subject matters, that a large sample size is an important component in research studies. The same is true for the Dermer et al. reference and its teaching that cell line data extrapolation is generally an unpredictable arena. Furthermore, the remaining rejections are also maintained for reasons of record in view of the non-entry of after final amendment.